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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
WACHTEL, EMILY L	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,004	BURKETT ET AL.	
	Examiner	Art Unit	
	EMILY WACHTEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *4,5,8,9 and 18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,10-17 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's confirmation of the election of Group I, Species A of Set I and Species X of Set II in the reply filed on June 17, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 4, 5 ,8, 9, and 18-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 17, 2008.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 6, 10, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Prather (U.S. Patent 5,404,887).

With regard to claim 1, Prather teaches an intraluminal guide wire (Fig. 1 guide 10), comprising; an elongated core (Fig. 1 core 12) having a proximal core section (Fig. 1 generally indicated at R2) and a distal core section (Fig. 1 section generally indicated at T3) having a distal end (Fig. 1 distal end at 13); wherein at least a section of the elongated core includes at least one of randomized and non-randomized tactile surface contours (Fig. 14 surface contours 78, Col. 2 lines 17-27, Col. 8 lines 47-49); an uninterrupted polymer coating with a generally consistent

outside diameter adhering to at least a portion of the elongated core and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated core (Fig.1 shows a generally constant outer diameter of the core, Col. 7 lines 46-54 discloses a polymer coating which would follow the contours of the core and would have a generally constant outer diameter as it followed the generally consistent outer diameter of the core); and a flexible tubular member disposed over the distal core section (Fig. 1 flexible member 14).

With regard to claim 3, the tactile surface contours include a bump (Fig. 14 contour 78, Fig. 3 contour 24).

With regard to claim 6, the tactile surface contours include a rib (Fig. 14 contour 78, Fig. 3 contour 24).

With regard to claim 10, the tactile surface contours include ridges and dips (Fig. 14 contour 78, Fig. 3 contour 24).

With regard to claim 15, the polymer coating is Teflon, a fluoropolymer (Col. 7 line 59).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 7, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prather (U.S. Patent 5,404,887) as applied to claim 1 above, and further in view of McMahon (U.S. Patent 6,296,616).

With regard to claim 2, Prather teaches an intraluminal guide wire substantially as claimed and further shows that the surface-to-peak amplitude of the contours would be .002 inches (Col. 5 lines 31-33 - the difference between the maximum outer diameter and minimum outer diameter yields the height of the surface contour), but Prather does not teach a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Prather, with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 7, Prather teaches an intraluminal guide wire substantially as claimed and further shows eight protrusions on a guide wire (Fig. Fig. 14 contour 78) and based on a guide diameter of .36 mm this ultimately places the protrusion about .015 cm apart. Prather does not disclose the spacing to range between .05 cm to 2 cm. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the number of

contours and thus the spacing of the contours to place it within a range of .05 cm to 2 cm because it would serve as a means to adjust the surface contact area and thus the friction to achieve a desired amount of frictional resistance. Further, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). The peaks of the contact regions have a spacing of .005 cm to .5 cm (Col. 2 lines 57-58) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Prather, with a spacing of about .05 to 2 cm as McMahon discloses an overlapping range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 16, Prather teaches an intraluminal guide wire (Fig. 1 guide 10), comprising; an elongated core (Fig. 1 core 12) having a proximal core section (Fig. 1 generally indicated at R2) and a distal core section (Fig. 1 section generally indicated at T3) having a distal end (Fig. 1 distal end at 13); wherein an exterior surface of the distal core section includes randomized tactile surface contours (The core can have the contours directly on it's surface as in Fig. 14 surface contours 78, or on sleeve which is included as a part of the core as in Fig 3 contours 24, Col. 2 lines 17-27, Col. 8 lines 47-49); a polymer coating adhering to at least a portion of the distal core section with a coating profile not following a tapered profile of the elongated core (Fig. 1 the elongated core 12 has an inner tapered profile and an outer sleeve 18 with contours 24, Fig. 3, thereby, the coating does not follow the tapered profile), the polymer

coating having randomized tactile surface contours following the randomized surface contours of the exterior surface of the distal core section (Fig.1 the polymer coating follows the exterior surface contours of the sleeve, Col. 7 lines 46-54 discloses a polymer coating which would follow the contours of the core); and a flexible tubular member disposed over the distal core section (Fig. 1 flexible member 14). Prather does not disclose the polymer coating to have a generally non-uniform thickness. However, McMahon discloses a guide wire with a coating of non-uniform thickness following the tapered profile of the core to create a constant outer diameter (Fig. 1 ref. numbers 11, 13, 15 - sheath 15 is taken to be equivalent to a coating as Meriam-Webster dictionary defines a coat as 'a layer of one substance covering another' which is embodied by the sheath, and it does not follow the tapered profile of the elongated core, Col. 2 lines 45-46 - sheath is polymeric material). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize a polymer coating with a non-uniform thickness in the guide wire of Prather because McMahon teaches this to create a constant outer diameter and in the case in Prather when the surface contours are directly on the tapered surface it would still allow for a constant outer diameter as desired when using the outer sleeve.

With regard to claim 17, the tactile surface contours include a rib (Fig. 14 contour 78, Fig. 3 contour 24).

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prather (U.S. Patent 5,404,887) as applied to claim 1 above, and further in view of Mageoh (U.S. Patent 3,731,671).

With regard to claim 11, Prather discloses an intraluminal guide wire substantially as claimed but does not show the surface contour to include a circumferential groove. However, Mageoh teaches a guide wire which will only contact the lumen it is being passed through at spaced apart points to reduce friction (Col. 1 lines 47-52, Fig. 3). The spaced apart points in the guide wire create circumferential grooves. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours in Prather that would yield a circumferential groove because Mageoh has shown such a contour to be an art effective means for reducing the surface contact between the guide wire and a lumen to reduce friction and such configurations would be art recognized equivalents.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prather (U.S. Patent 5,404,887) as applied to claim 1 above, and further in view of Richardson et al. (WO 01/36034).

With regards to claims 12 and 13, Prather teaches a coated guide wire substantially as claimed but does not disclose the flexible tubular member disposed over the polymer coating, as in claim 12, or the coating disposed over the flexible tubular member as in claim 13. However, Richardson et al. discloses a coated guide wire with a flexible tubular member (Fig. 1 core member 11, proximal section 12, distal section 13, flexible member 14, coating 19). Richardson et al. teaches the coating can be applied anywhere along the core, thus, the flexible guide member would be over the coating (Pg. 20 lines 3-6) and additionally the coating can be applied over the flexible guide member, thus, the coating is disposed over the flexible guide member (Pg. 20 lines 3-6). This provides a lubricious coating to reduce friction. It would have been obvious

to a person of ordinary skill in the art at the time the invention as made to dispose the flexible guide over the polymer coating, or the coating over the flexible guide in the device of Prather because Richardson et al. teaches such coatings to be lubricious and applied in any configuration to a guide wire and further it would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the placement of the coatings in order to achieve a desired amount of frictional resistance.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prather (U.S. Patent 5,404,887) as applied to claim 1 above, and further in view of Murayama et al. (US 2004/0039309).

With regard to claim 14, Prather discloses an intraluminal guide wire substantially as claimed but does not disclose the proximal core section to include high strength steel and the distal core section to include nickel-titanium alloy. However, Murayama et al. teaches a guide wire with a distal and proximal portion joined by welding (Pg. 1 [0009]). The two sections are made from different alloys (Pg. 4 [0070]), the distal section (Fig. 1 section 2) is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section (Fig. 1 section 3) is made from a stainless steel (Pg. 4 [0071]). This causes the distal portion to have high flexibility and the proximal portion to have a high rigidity and, therefore, the guide wire has a high flexibility and high torque transmission which enhances the operationability of the wire (Pg. 4 [0070]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create the guide wire in Prather so the proximal core section to include high strength steel and the distal core section to include nickel-titanium alloy because Murayama et al. teaches

that this gives the guide wire a high flexibility and high torque transmission which enhances the operationability of the wire.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prather (U.S. Patent 5,404,887) in view of McMahon (U.S. Patent 6,296,616), Richardson et al. (WO 01/36034), and Murayama et al. (US 2004/0039309).

With regard to claim 31, Prather teaches an intraluminal guide wire (Fig. 1 guide 10), comprising; an elongated core (Fig. 1 core 12) having a proximal core section (Fig. 1 generally indicated at R2) and a distal core section (Fig. 1 section generally indicated at T3) having a distal end (Fig. 1 distal end at 13); wherein an exterior surface of the distal core section includes randomized tactile surface contours (The core can have the contours directly on it's surface as in Fig. 14 surface contours 78, or on sleeve which is included as a part of the core as in Fig 3 contours 24, Col. 2 lines 17-27, Col. 8 lines 47-49); a polymer coating adhering to at least a portion of the distal core section with a coating profile not following a tapered profile of the elongated core (Fig. 1 the elongated core 12 has an inner tapered profile and an outer sleeve 18 with contours 24, Fig. 3, thereby, the coating does not follow the tapered profile), the polymer coating having randomized tactile surface contours following the randomized surface contours of the exterior surface of the distal core section (Fig.1 the polymer coating follows the exterior surface contours of the sleeve, Col. 7 lines 46-54 discloses a polymer coating which would follow the contours of the core); and a flexible tubular member disposed over the distal core section (Fig. 1 flexible member 14). Prather does not disclose the polymer coating to have a generally non-uniform thickness. However, McMahon discloses a guide wire with a coating of

non-uniform thickness following the tapered profile of the core to create a constant outer diameter (Fig. 1 ref. numbers 11, 13, 15 - sheath 15 is taken to be equivalent to a coating as Meriam-Webster dictionary defines a coat as 'a layer of one substance covering another' which is embodied by the sheath, and it does not follow the tapered profile of the elongated core, Col. 2 lines 45-46 - sheath is polymeric material). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize a polymer coating with a non-uniform thickness in the guide wire of Prather because McMahon teaches this to create a constant outer diameter and in the case in Prather when the surface contours are directly on the tapered surface it would still allow for a constant outer diameter as desired when using the outer sleeve. Prather teaches an intraluminal guide wire substantially as claimed and further shows that the surface-to-peak amplitude of the contours would be .002 inches (Col. 5 lines 31-33 - the difference between the maximum outer diameter and minimum outer diameter yields the height of the surface contour), but Prather does not teach a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Prather, with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*,

105 USPQ 233. Prather does not disclose the flexible tubular member disposed over the polymer coating. However, Richardson et al. discloses a coated guide wire with a flexible tubular member (Fig. 1 core member 11, proximal section 12, distal section 13, flexible member 14, coating 19). Richardson et al. teaches the coating can be applied anywhere along the core, thus, the flexible guide member would be over the coating (Pg. 20 lines 3-6) and additionally the coating can be applied over the flexible guide member, thus, the coating is disposed over the flexible guide member (Pg. 20 lines 3-6). This provides a lubricious coating to reduce friction. It would have been obvious to a person of ordinary skill in the art at the time the invention as made to dispose the flexible guide over the polymer coating in the device of Prather because Richardson et al. teaches such coatings to be lubricious and applied in any configuration to a guide wire and further it would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the placement of the coatings in order to achieve a desired amount of frictional resistance. Prather does not disclose the proximal core section to include high strength steel and the distal core section to include nickel-titanium alloy. However, Murayama et al. teaches a guide wire with a distal and proximal portion joined by welding (Pg. 1 [0009]). The two sections are made from different alloys (Pg. 4 [0070]), the distal section (Fig. 1 section 2) is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section (Fig. 1 section 3) is made from a stainless steel (Pg. 4 [0071]). This causes the distal portion to have high flexibility and the proximal portion to have a high rigidity and, therefore, the guide wire has a high flexibility and high torque transmission which enhances the operationability of the wire (Pg. 4 [0070]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create the guide wire in Prather so the proximal core section to include

high strength steel and the distal core section to include nickel-titanium alloy because Murayama et al. teaches that this gives the guide wire a high flexibility and high torque transmission which enhances the operationability of the wire. Prather teaches the polymer coating is Teflon, a fluoropolymer (Col. 7 line 59).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 6-7, and 10-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, and 9-13 of copending Application No. 11/762,617. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are not structurally distinguishable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed June 17, 2008 have been fully considered but they are not persuasive. Regarding the Applicant's argument that Prather does not teach surface contours on the elongated core, the Examiner respectfully disagrees. Initially, Fig. 14 does illustrate a raised surface directly on a guidewire and does not indicate a sleeve. Regardless, the sleeve and core members taken together, represent the entire elongated core and as such the elongated core includes surface contours. The language of the claim does not exclude the sleeve and core from being taken together to embody an elongated core. Alternatively, the sleeve itself could be construed as the elongated core. Further, regarding the Applicant's holding that the distal core section in McMahon is smooth, such is immaterial to the rejection at hand as such is not relied upon for the purposes of the rejection.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767